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General Best Practice Guidance for Food Establishments and Regulatory Authorities for Digital Food Safety Management Systems

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A. Introduction and Scope

The use of Digital Food Safety Management Systems (DFSMS) within the retail food industry, regulated by the Food and Drug Administration (FDA), continues to gain widespread interest, acceptance, and use. The use of DFSMS is expected to continue to grow in the retail food industry as technology improves and components become more readily available. As technology advances the retail food industry continues to replace paper-based records associated with traditional food safety management systems with digital documentation. Recent FDA Risk Factor study results have shown that utilizing a robust management system leads to a reduction in food safety risk factors.

An oft-used component of a DFSMS, Digital Temperature Monitoring Equipment (DTME) can improve awareness, response, and documentation of temperature conditions. This technology allows more accurate, reliable, and efficient food and equipment temperature control impacting safety and quality improvements. As DFSMS and DTME become more common in the retail food industry, the visibility, awareness, and availability of information that these systems and technology can provide should support improvements in controlling food safety risk factors in food retail.

This guidance will outline food safety management approaches specific to the implementation and use of technology in food retail. Best practices provided in this document serve as a foundational guide for the collection of accurate, consistent, and reliable data that can be used to make risk-reduction decisions. This document has been written with the assumption that a food retail establishment has a food safety management system and that they have identified and addressed HACCP Principles 1, 2 and 3 as referenced in Annex 4 of the most recent version of the U.S. FDA Model Food Code.

B. Definitions

Digital Food Safety Management System (DFSMS)

An interactive, digital, or electronic archive intended to collect, store, and analyze data that supports a food safety management system as defined in Annex 4 of the most recent version of the U.S. FDA Model Food Code. DFSMS specifically supports ongoing quality control and assurance, monitoring and recordkeeping of specific food safety goal-oriented plans, like Risk Control Plans (RCPs), that outline procedures for controlling foodborne illness risk factors. A DFSMS is intended to enable a proactive approach to support the consistent safe production, transport, preparation, storage, and service of safe wholesome food as defined in the most recent version of the FDA model Food Code. A DFSMS employs active user-based workflows that support decision making, that can be reviewed and acted upon, and may be housed locally (on-premises) or be accessed remotely using off-site servers or cloud storage.

DFSMS may include but are not limited to functionality that allows a user to:

- capture, record, and store multiple types of data
- provide real-time feedback to users
- generate record keeping reports (i.e., Trends over time)

Other components, tools, and records within a DFSMS may include:

- specific policies, procedures, recipe cards, and critical limit monitoring actions and corrective actions including training tools
- risk control plans
- product storage/movement information and inventory supporting recalls and market withdrawals
- equipment maintenance documentation
- active alerting
- networked and/or IOT devices

Digital Temperature Monitoring Equipment (DTME)

Automated purpose-built temperature measuring device(s) that often includes sensors capable of generating and capturing temperature data for analytical use. This equipment may include the functionality of automatically measuring, monitoring, storing, transmitting, documenting, and sharing the temperature of food, air, or water. Monitoring equipment that captures and stores temperature data over a period of time that may connect to a system that may be capable of delivering alerts and exception reports.

Software

Software is the term used to describe the total set of programs, procedures, rules, and any associated documentation pertaining to the operation of a technology-based system that

includes, but is not limited to application, operating system, and utility applications used by the computerized system.

C. Prerequisites

Best practice for a DFSMS is to employ purpose-built hardware and software when designing and implementing an approach. The appropriateness of hardware and software should meet the goals of any RCP. Maintenance of the system and the proper replacement of system hardware is critical for it to function as designed. Design specifications of the hardware and software should be determined and periodically reviewed to ensure the system and its functional components do what is intended to support food safety.

This document recognizes that DFSMS are built and utilized to support the most recent version of U.S. FDA Model Food Code, Annex 4, HACCP Principles specifically:

Principle #4: Establish Monitoring Procedures
Principle #5: Establish Corrective Actions - implementation of the corrective action specifically
Principle #6: Verification/Sharing for equivalency for regulatory checks
Principle #7: Record keeping procedures and documentation

Personnel operating, maintaining, and programming DFSMS should have adequate training to complete their assigned duties. Determine the extent of operator, system managers, and software system technical personnel training in the functions, requirements and operation of the computerized system.

Examples of training may include but are not limited to:

- system operation
- malfunctions
- regulatory requirements
- system changes
- security procedures
- manual operation of the system
- documentation of system errors

D. DFSS Inputs

Digital Food Safety System Equipment (DFSSE)

DFSSE typically include various purpose-built and designed stationary and handheld measurement instruments, tools, and sensors capable of the collection, storage, and

transmission of data into software. The food contact surface of DFSSE must meet the design and placement characteristics in Chapter 4 of the most recent version of the U.S. FDA Model Food Code and must be designed to meet or exceed NSF Standard 2 - Food Equipment or equivalent. Examples may include but are not limited to mobile device(s), sensors, thermometers, RFID/QR Code scanner/receiver, etc.

Stationary Monitoring Devices

Purpose build devices which are permanently or semi-permanently affixed, mounted, installed, attached to equipment or surface using food grade mounting/installing materials, maintained free of accumulated soil, and cleaned per manufacturer instructions. When devices do not include an external measurement display, access to the measurement data should be easily accessible and viewable. These devices when appropriate should meet the design and placement characteristics in Chapter 4 of the most recent version of the U.S. FDA Model Food Code and must be designed to meet or exceed NSF Standard 2 - Food Equipment or equivalent.

> *Note: DFSS Stationary temperature monitoring devices must meet the requirements outlined in the most recent version of the U.S. FDA Model Food Code 4-204.112 Temperature Measuring Devices*.

Device examples may include but are not limited to equipment or wall mounted data loggers, humidity sensors, door open/close sensors, camera's, etc.

Data access examples may include but are not limited to: Software report on mobile, desktop, tv monitor/screen, etc.

DFSSE Accuracy

Handheld and stationary temperature measurement instruments must meet the most recent version of the U.S. FDA Model Food Code 4-203.11 & 4-203.12. In the event that a handheld or stationary temperature device does not have a display; the operator should be able to easily demonstrate/record the reading/actual monitored temperature (value) for review and record. Follow OEM recommendations & guidelines and follow their procedures.

DFSSE Functionality

Regular and ongoing equipment and system operation functionality are recommended to be conducted (refer to manufacturer for frequency) to verify that DFSMS, DFSSE and DTME in use are operating as intended, if/when issue(s) are identified appropriate action is taken to correct issue(s).

Examples of device functionality issues are but are not limited to:

- Power loss
- Improper device installation
- Device damage/defective

- Software communication/connectivity
- Device communication/connectivity

It is recommended that records of software and equipment functionality verification be maintained and readily available.

Examples of functionality verification may include but are limited to:

- Handheld measurement device accuracy & functionality
- Stationary measurement device accuracy & functionality
- Software and device connectivity/communication

E. Data and System Infrastructure

DFSMS data are the measurement values and user inputs captured by DFSSE, DTME and DFSMS users that are then stored in DFSMS software. Data storage may be stored locally (on-site) or virtually (cloud storage) but access to this data must be readily available for use and display on-site. This makes it possible to retrace which value occurred at which time.

Examples of, but not limited to, measurement values that may be recorded and stored as data in a DFSMS:

- Time points and Account IDs which are assigned to certain quality checks
- Description of the area
- Description of the equipment
- Description of the products/product categories
- Description of the measurement locations of the equipment
- Description of suppliers
- Check lists/Quality handbook
- Tasks (Daily, Shift, On-Demand)
- Reports (Daily, Shift, On-Demand)
- Product specific quality and safety measurement data points (Temperature, pH, TPM, PPM, humidity, time)
- Alerts (alerts are notifications to users)
- Alarms (is the result of an unacceptable software or hardware reading)
- Alert recipients
- Corrective actions associated with checklists and measurement points
- Manual data entry (for immutability and data integrity)

When DFSSE, DTME or a DFSMS user completes a measurement this value is stored in DFSMS software. Each measurement value represents a unique permanent data point represented in the DFSMS software, additional or new data (including that which is associated with an existing or old data point) are then stored in a sequential manner allowing for the original data point to remain. This can be described as a time-based progression of record keeping. The DFSMS software should also be capable of recording all previously recorded data should be readily accessible and documented when changed and available for reporting.

Digital Temperature Monitoring Equipment (DTME) Data

There are three broad ways of capturing temperature and humidity data; they are commonly identified as hand-held, stationary, or Integrated temperature measuring devices. An important consideration for DTME is that devices have the ability to cache/store data locally when connectivity is interrupted, if/when data connectivity is interrupted a DTME device should have the ability to push/send cached/stored data to the DFSMS system when connectivity is restored.

Verification / Immutability

A retail food business may have measures in place to ensure that data captured by the computerized system cannot be altered without a digital signature record or other means of tracking history of inputs. If provisions are made to allow correction of data entries, the entry may identify the person making the changes, the reason for the change and reference to the originally captured data.

Data and System Integrity and Access

Data Integrity and Access are both important aspects of a DFSMS that should be considered to ensure that quality of the information collected by the system is accurate and reliable. To support the integrity of a DFSMS it is recommended that reasonable controls are in place to ensure that stored and/or in-process data is not able to be altered in an unauthorized manner, and that any changes to the DFSMS and/or the stored/in-process data is captured.

Data access is also a way to support effective data integrity. Access to a DFSMS should be controlled and limited only to those persons to whom permission is granted. All data and information should be protected through reasonable use of encryption protocols.

Examples of encryption may include, but are not limited to:

- Utilizing passwords,
- User management and,
- User rights.

Examples of information and/or data for encryption include but are not limited to:

- Passwords
- Proprietary business information
- Data transferred between the input devices and local/cloud-based reporting and storage programs/locations.
- Login occurrences
- Access to information within the DFSMS should also be tailored according to a user's role and responsibilities, writing, or reading rights.

Manual Data Entry

Determine if and how manual interventions are documented; a separate log may be kept of such interventions. The computerized system may be such that it detects, reacts to, and automatically records manual interventions. It is important that system operators are trained in manual backup systems as a best practice this should be documented and conducted prior to DFSMS usage. To ensure business continuity, it is recommended that users have their own SOP for review (redundancy) to ensure practices are being enacted.

Manual Back-Up

A manual back-up system is frequently utilized as a function of business continuity in the event of a computerized system (e.g., hardware or software) failure. Functions controlled by computerized systems may sometimes also be controlled by parallel manual backup systems. As a best practice, functions that are manually controlled and/or manually backed up should be identified and noted re: the firm’s protocols or the system’s protocol. Critical process controls are particularly important. Determine the interaction of manual and computerized controls and the degree to which manual intervention can override or defeat the computerized function. The firm's operating instructions should describe what manual overrides are allowed, who may execute them, how and under what circumstances.

F. DFSMS Outputs

System Outputs and Notification(s)

Typical DFSMS and DTMS include the capability to include user level notification(s) tailored around programmable components of an organization's Standard Operating Procedures (SOP), see What Data is Stored section above for measurement examples that may be involved.

Examples of user level system notification(s) may include but are not limited to the following:

- Reports
- Trends
- Automated emails
- SMS or text message
- Phone calls
- Visual indicators (lights)
- Audible indicators (sounds)

A best practice is to associate one or more corrective actions with an alert. To assure corrective actions are completed in a timely fashion, alerts can be escalated when corrective actions are not completed within a set timeframe.

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